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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TOTH, KAREN E

ART UNIT

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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,412	Applicant(s) ASANO ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11-24,26-28,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9,11-20,22,24,26-28,37 and 38 is/are rejected.
- 7) ☒ Claim(s) 21 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 1, 4, 7, 13, 15, 17, 18, 24, 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Berner (US 6144869).

Regarding claim 1, Berner discloses a device comprising a first electrode part (elements 4, 8, 12), a through-current electrode part (element 14), and a power supply part for supplying electrical energy to the electrode parts to extract an analyte in the first electrode part (column 7, lines 55-59; column 16, lines 40-42), wherein the first electrode part comprises a first electrode connected to the power supply part (element 12), and a collection material connected to the electrode for collecting an analyte extracted by the first electrode (elements 4, 8), wherein the first collection material is configured to contact the skin over an area of between 0.01 and 25 mm² (column 20, lines 6-25).

Regarding claim 4, Berner further discloses that the power supply part supplies a current of less than about 300 uA (column 18 line 65 to column 19 line 1; column 20 line 24).

Regarding Claim 7, Berner further discloses that the electrode part is detachable from the power supply part (column 17, lines 53-55), since a non-rechargeable battery must be removed (detached) in order to allow replacement.

Art Unit: 3735

Regarding Claim 13, Berner further discloses that the power supply part may be a constant-voltage power supply (column 17, lines 53-55), because a battery supplies constant voltage.

Regarding Claim 15, Berner further discloses that the device may comprise a part for accelerating or promoting analyte extraction (column 8, lines 26-40).

Regarding Claim 17, Berner further discloses that the analyte is glucose (column 10 line 67 to column 11 line 1).

Regarding Claim 18, Berner further discloses that the overall system comprises an assay part for assaying the analyte extracted in the first electrode part and for outputting a signal corresponding to the analyte's concentration (column 18, lines 47-54); an analysis part for analyzing the concentration signal (column 17, lines 36-49); and an output part for outputting the analysis result (column 17, lines 36-49).

Regarding Claim 24, Berner discloses a method comprising placing two electrode parts on skin (column 4, lines 1-23); applying electrical energy to the electrode parts (column 8, lines 41-54); and extracting analyte at the first electrode part (column 8, lines 26-54); wherein the first electrode part comprises an electrode connected to the power source (element 12), and a collection material (elements 4 and 8) that is connected to the electrode (figure 1B) and which is configured to contact the skin over an area of between 0.01 and 25 mm² (column 20, lines 6-25).

Regarding Claim 28, Berner further discloses that the method comprises outputting a signal corresponding to the analyte's concentration (column 9, lines 14-31);

Art Unit: 3735

analyzing the concentration signal (column 17, lines 36-49); and outputting the analysis result (column 17, lines 36-49).

3. Claims 3, 8, 9, 11, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berner in view of Avrahami (US Patent Application Publication 2004/0230227).

Regarding Claim 3, Berner discloses all the elements of the current application, as described above, except for the current flowing from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part. Avrahami discloses a transdermal analyte extraction device comprising a through-current electrode and a first electrode (elements 120 or 124) and a power supply (elements 50 and 98), wherein the current flows from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part (Figure 4), in order to more efficiently extract analytes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner with the specific current flows of Avrahami, in order to more efficiently extract analytes.

Regarding claims 8 and 9, Berner discloses all the elements of the current application, as described above, except for the device comprising a second electrode part having the same contact area as the first electrode part, and the power supply part of the device comprising power supplies for both the first and second electrode parts. Avrahami discloses a transdermal analyte extraction device comprising a plurality of

Art Unit: 3735

identical electrode parts (Figure 2), each with a power supply (Figure 4), in order to more thoroughly sample analytes from a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner, with additional identical electrodes, each with a power supply, as taught by Avrahami, in order to more thoroughly sample analytes from a patient.

Regarding Claim 11, Berner in view of Avrahami discloses all the elements of the current invention except for the first and second electrode parts being integrated. Avrahami further discloses that the plurality of electrode parts are integrated within a single housing (Figure 2), in order to facilitate application upon a patient's skin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner in view of Avrahami, and integrated the electrode parts, as taught by Avrahami, in order to facilitate application upon a patient's skin.

Regarding Claim 26, Berner discloses all the elements of the current invention, as described above, except for the method comprising placing a second electrode part having the same collection material contact area as the first electrode part on the skin, supplying it with electrical energy, and extracting analyte at the duplicate electrode. Avrahami discloses a method of transdermal analyte extraction comprising a placing a plurality of identical electrode parts (Figure 2) on a patient's skin, each with a power supply (Figure 4), and using them to transdermally extract analyte, in order to more thoroughly sample analytes from a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of

Art Unit: 3735

Berner, with the steps of adding, powering, and sampling from additional electrodes, as taught by Avrahami, in order to more thoroughly sample analytes from a patient.

Regarding Claim 27, Berner in view of Avrahami discloses all the elements of the current invention, as disclosed above, except for the first and second electrode parts being placed on the skin substantially simultaneously. Avrahami further discloses that the plurality of electrode parts are disposed within a single housing (Figure 2) and are therefore placed on the skin substantially simultaneously, in order to more efficiently apply the sampling apparatus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Berner in view of Avrahami, and applied the electrode parts simultaneously, as taught by Avrahami, in order to more efficiently apply the sampling apparatus.

4. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berner in view of Ackerman (US Patent Application Publication 2003/0208114).

Regarding Claim 12, Berner discloses all the elements of the current invention, as described above, except for the power supply part supplying constant current. Ackerman discloses a device for transdermal analyte extraction comprising a part to supply direct (constant) current, in order to facilitate analyte extraction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner, with a constant current power supply, as taught by Ackerman, in order to facilitate analyte extraction.

Regarding Claim 16, Berner discloses all the elements of the current invention, as described above, except for the extraction acceleration part comprising ultrasonic irradiation. Ackerman discloses a device for transdermal analyte extraction comprising a part to apply ultrasonic irradiation, in order to facilitate analyte extraction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner with the part for applying ultrasonic irradiation, as taught by Ackerman, in order to facilitate analyte extraction.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berner in view of Glikfeld (US Patent 5279543).

Berner discloses all the elements of the current invention, as described above, except for the power supply part outputting a voltage of less than about 10 V. Glikfeld teaches a device comprising a pair of electrodes for extraction of an analyte, where the power supplied by a power supply part is less than about 10 V (column 7, lines 63-64), in order to prevent harm to the patient from excess voltage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Berner and used the power supply part to output a voltage of less than about 10 V, as taught by Glikfeld, in order to prevent harm to the patient from excess voltage.

6. Claims 19, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US Patent 6736777) in view of Burson (US Patent Application Publication 2003/0199745) and Berner.

Art Unit: 3735

Regarding claims 19 and 20, the examiner notes that the device of Kim is capable of being used as claimed because the device comprises a first electrode (element 40); an electrode for extracting an analyte (element 42); a through-current electrode (element 44); and a power supply used to supply power to all the electrodes (column 18, lines 11-20), where the first path-forming electrode part comprises a first electrode connected to the power supply part (element 40) and a chamber comprising water/ion-conductive material in contact with the electrode (column 9 lines 37-60; column 10, lines 34-36 and 44-67). Kim does not disclose the water being purified water, nor the particular contact area of the conductive material. Burson teaches a device for extracting an analyte using an electrode comprising a water/ion-conductive material in contact with the electrode (paragraph [0095]), in order to efficiently collect the analyte. Berner teaches using an electrode system with a collection material configured to contact skin over an area of less than 25 mm^2 (column 20, lines 6-25), in order to increase the efficiency of collection. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Kim with purified water, as taught by Burson, and a contact area of less than 25 mm^2 , as taught by Berner, in order to efficiently collect the analyte.

Regarding Claim 22, Kim further discloses a second identical set of electrodes, and a power supply used to supply power to all the electrodes (column 18, lines 11-20).

Art Unit: 3735

7. Claims 37 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Avrahami (US 2002/0058936).

Regarding claim 37, Avrahami discloses a method of extracting an analyte from living tissue (paragraph [0002]) comprising forming analyte transmission paths in the skin for passage of the analyte (paragraph [0166] - ablation of the stratum corneum by the electrode tip creates channels for extraction of analytes), placing a through-current electrode and an extraction electrode part on the skin (paragraph [0161]), and supplying electrical energy to the electrode parts to extract analyte at the first extraction electrode part (paragraph [0161]), wherein the first extraction electrode part is configured to contact the skin over an area of between 0.01 and 25 mm² (paragraph [0166] - a cone having a length of 150 microns and a base diameter of 500 microns results in a cone with a surface area of 425330.5 square microns, or 0.4 mm²).

Regarding claim 38, Avrahami discloses a device for extracting an analyte from living tissue (paragraph [0002]) comprising a through-current electrode and an extraction electrode (paragraph [0161]), and a power supply part (element 130) supplying electrical energy to the electrode parts to extract analyte at the first extraction electrode part (paragraph [0161]), wherein the first extraction electrode part is configured to contact the skin over an area of between 0.01 and 25 mm² (paragraph [0166] - a cone having a length of 150 microns and a base diameter of 500 microns results in a cone with a surface area of 425330.5 square microns, or 0.4 mm²).

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the structure of claims 21 and 23, including, *inter-alia*, connecting the path-forming electrode part to a power supply only during path forming, and disconnecting it when extracting analyte, in combination with all other limitations in the claims.

Response to Arguments

9. Applicant's arguments, see the remarks filed 31 August 2009 have been fully considered and are persuasive. Therefore, the previously presented rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made above.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kurnik (US 2003/0120138), which discloses extraction electrodes with contact surface areas of between 0.01 and 25 mm², and Nguyen (US 2004/0167418) and Fischer (US 2004/0193089), which also disclose similarly sized electrodes.

Art Unit: 3735

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735